

REMARKS

Claims 7-17, 18-31, 33, and 34 are pending in the present application.

The rejection of Claims 7-34 under 35 U.S.C. §112, first paragraph (enablement), is respectfully traversed.

The present invention provides, *inter alia*, an isolated nucleic acid encoding an alkaline protease having an amino acid sequence which is at least 90% homologous to an amino acid sequence of either SEQ ID NO: 1 (see Claim 7) or SEQ ID NO: 2 (see Claim 21), wherein said isolated alkaline protease has alkaline protease activity.

In the outstanding Office Action the Examiner has held that the specification fails to enable the scope of homologs defined by "at least 90% homologous to an amino acid sequence of SEQ ID NO: 1 (or 2)." Applicants disagree and note that there are several recitations of a range of homology of at least 90% homologous to SEQ ID NOs: 1 or 2.

MPEP § 2164.01 states:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Applicants submit that determining what sequences fall within or without the scope of present Claims 7-34 would be readily apparent to the skilled artisan *without* undue experimentation when these claims are read in view of the specification, as well as the knowledge generally available in the art.. The Examiner's attention is drawn to pages 5-7, which provides a description of the scope of homology permissible in the claimed alkaline protease. Further, the Examiner's attention is drawn to the Table appearing on page 6 of the specification, which provide guidance for the artisan by providing a detailed listing of preferable amino acids for each Xaa within the claimed amino acid sequences (in particular SEQ ID NO:2). At

pages 7-12, Applicants describe the method by which the claimed amino acid sequences may be cloned, expressed, and isolated. Moreover, at pages 14-45, Applicants provide a detailed example of how the skilled artisan may clone, express, and characterize any sequence variant to assess its standing with respect to the claimed invention.

MPEP §2164.04 states:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In view of the specifically highlighted pages in the specification (supra), Applicants submit that they have met their burden to enable the skilled artisan to obtain an isolated alkaline protease having an amino acid sequence which is at least 90% homologous to an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 2, wherein said isolated alkaline protease has alkaline protease activity.

In fact, the Examiner's attention is directed to the fact that the Office has already recognized the sufficiency of the present disclosure to support enablement of "An isolated alkaline protease having an amino acid sequence which is at least 90% homologous to an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 2, wherein said isolated alkaline protease has alkaline protease activity." (see Claim 1 of the parent application, U.S. 6,759,228) Therefore, the Office cannot now take a contrary position.

Further, it cannot be the Office's position that the skilled artisan would not be able to convert the amino acid sequence into a polynucleotide sequence encoding the recognized enabled scope of protein homologs. With respect to polynucleotides encoding a protein

falling within the scope defined in Claims 7 and 21, Applicants submit that the universal code has been known in the art for several decades. The fact that it is published in every high school biology text book clearly evidences the fact that much less than basic skill is required to convert the amino acid sequence of a protein within the scope defined in Claims 7 and 21 into the corresponding polynucleotide sequences. As such, no more than routine skill is required to practice the present invention.

Based on the foregoing, Applicants submit that the present claims are fully enabled by the specification and the common knowledge available in the art and as such withdrawal of this ground of rejection is requested.

The rejections of Claims 18 and 32 under (a) 35 U.S.C. §112, second paragraph, and (b) 35 U.S.C. §112, first paragraph (enablement), are obviated by amendment.

Claims 18 and 32 have been canceled. As such, these grounds of rejection are believed to be moot.

Withdrawal of these grounds of rejection is requested.

Applicants respectfully request that the obviousness-type double patenting rejections of Claims 7-34 over: (a) Claims 4-20 of U.S. 6,376,227, and (b) claims drawn to "a gene" in co-pending Application Nos. 10/456,479, 10/820,712, 10/820,714, 11/235,249, and 11/318,576, be held in abeyance until an indication of allowable subject matter in the present application. If necessary, a terminal disclaimer will be filed at that time. Until such a time, Applicants make no statement with respect to the propriety of this ground of rejection.

Application Serial No.: 10/784,870  
Response to Office Action mailed June 12, 2006

Finally, Applicants have updated the cross-reference to related applications to update the status of the parent applications.

Applicant submits that the application is now ready for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon



Vincent K. Shier, Ph.D.  
Registration No. 50,552

Customer Number

**22850**

Tel: (703) 413-3000  
Fax: (703) 413-2220  
(OSMMN 08/03)